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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,265	11/28/2000	Bruce Marvin Held	NI205-008	7900

6449 7590 01/30/2003

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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/724,265

Applicant(s)

HELD ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,6,21-55 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 7-10, 13-20, 56-61 and 63-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6. 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Restriction election***

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 10, filed 21 August 2002. Applicant elects Group I, (B) (a), claims 1-20 and 56-65, directed to nucleotide sequences and plant cells, with traverse. Applicant traverses, stating only that the inventions are not patently distinct, submitting no evidence or argument otherwise. Applicant's traversal has been considered and is unpersuasive because no evidence or grounds for traversal are presented by Applicant.
2. Claims 3, 5, 6, and 21-55 and 62 are withdrawn as belonging to a non-elected invention.
3. Claims 1, 2, 4, 7-20, 56-61 and 63-65 are examined in the instant application. This restriction is made FINAL.

***Information Disclosure Statement***

4. An initialed and dated copy of Applicant's IDS forms 1449, Papers No. 5, and 6, filed 27 August 2001, and 26 November 2001, respectively, is attached to the instant Office action.

***Claim Rejections - 35 USC § 112-second***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 4, 7-20, 56-61 and 63-65 are rejected under 35 U.S.C. 112-2<sup>nd</sup>.

In claim 1 (c) "aerosol droplets" lacks antecedent basis

Claims 1, 19 and 20 are incomplete methods because the desired product is not produced in the final step of the method.

Clarification and/or correction are required.

***Claim Rejections - 35 USC § 112, first paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 17 lists five DNA vectors, however, the specification gives only the various named vectors and does not give sequence information on the vectors. Therefore, even if one skilled in the art constructed such a described vector, it would not necessarily have the same sequence as the named vector.

The specification lacks sufficient evidence that the claimed biological material is either 1) reproducible, 2) known and readily available to the public, or 3) deposited in compliance with 37 C.F.R. 1.801-1.809. If the claimed biological material were

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deposited under the provisions of the Budapest Treaty, Applicant must provide a declaration stating that the claimed biological material was made under the provisions of the Budapest Treaty in compliance with 37 CFR 1.801-1.809, and that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of the patent. Applicant's attention is directed to 37 C.F.R. §§ 1.801-1.809, M.P.E.P. §§ 2402-2411.05 and In re Lundak, 773 F.2d. 1216, 227 U.S.P.Q. 90 (Fed. Cir. 1985) for further information concerning the Rules and Regulations for Deposit of Biological Materials for Patent Purposes.

***Claim Rejections - 35 USC § 102/103***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1,2, 4, 7-10, 13-20, 56-57, 61, and 63 are rejected under 35 U.S.C. 102

(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mets, US 5,240,842, issued August 31, 1993.

Mets teaches a method of introducing molecules into a plant cell (Abstract, for example), comprising preparing a solution of nucleic acid (Abstract), supplying the solution for conversion to aerosol droplets at a flow rate (Abstract), producing aerosol droplets comprising the nucleic acid, accelerating the droplets toward the cell, and impacting the cell with the droplets (Claim 1 (c) and (d)), where the molecules are

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nucleic acid (claim 2), where the cell is a plant cell (Abstract), where the plant cell is a corn cell (claim 4), where the aerosol droplets are less than 0.1 micron in diameter (col 5, lines 20-22; claim 3), where the droplets are continuously targeted, where the target surface can be controlled, where the nucleic acid is a vector (col 11/lines 22-30), the use of a microflow nebulizer (col 8, lines 60-65), regenerating a transgenic plant (col 3, line 67), and progeny of the plant (col 4, line 2).

11. Claims 1, 2, 4, 7-10, 13-20, 56-57, 61, and 63 require limitations of a flow rate which has the property or characteristic of being various rates between 1 microliter/minute to 350 microliter/minute. Mets teaches introducing molecules into a cell as claimed in the instant invention but does not recite any specific flow rate. The Examiner is unable to determine whether the prior art disclosure possesses the unrecited characteristics or property, since the Mets patent is silent on aerosol flow rates. However, the method of Mets used an aerosol flow rate which enabled the introduction of nucleic acids into a plant cell. With these conditions, where the method seems to be identical except that the prior art is silent to the characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

Accordingly, Mets anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1,2, 4, 7-10, 13-20, 56-58, 60, 61, and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mets as discussed above, and further in view of Pui, et al, WO 98/56894, publication date 17 December 1998.

Mets teaches the claimed method of introducing a molecule into a plant cell, as stated above. Mets does not specifically teach an aerosol flow rate or 1 microliter/minute to 350 microliters/minute. Pui teaches flow rates of "about 0.01 microliter/minute to about 5 microliters/minute" (p 36, lines 2-3) in a method of introducing a molecule into a cell. The Office interprets 8 microliters/minutes to be "about 5 microliters/minute".

Given the recognition of one of ordinary skill in the art, of the value of introducing a nucleic acid molecules into a plant cell, as taught by Mets, one of ordinary skill in the art would have been motivated to used the specific flow rates taught by Pui for the introduction of nucleic acids into a cell. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary. Accordingly, the claimed invention is prima facie obvious in view of the prior art.

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**Remarks**

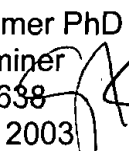
14. No claim is allowed.

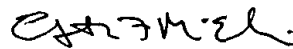
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD  
Patent Examiner  
Art Group 1638  
January 24, 2003



  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600